DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed August 5, 2011 has been entered. Claims 4, 17 and 21-28 have been canceled. Claims 1, 9 and 16 have been amended. Claims 1-3, 5-16, 18-20 and 29 are under examination.

Rejections Withdrawn

2. In view of Applicant's amendments and remarks the following rejections are withdrawn:

(a) rejection of claims 1-3, 10-16, 19-20 and 29, pages 2-9, paragraph 3 of the Final Office action.

(b) rejection of claims 1-3, 5-16, 18-20 and 29, pages 9-15, paragraph 4 of the Final Office action.

New Grounds of Rejection

Provisional Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 6-16, 18-20 and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 27 and 34 of copending Application No. 12/256, 665 filed January 18, 2005 in view of Mathew et al *(Headache 2002, 42;454, Abstract S107).*

This is a provisional obviousness-type double patenting rejection.

This application is drawn to a method of treating an acute pain medication overuse disorder caused by overuse of acute pain medication by administering botulinum toxin to the patients. Co-pending application 12/256,655 is drawn to a method for treating a

headache in a triptan medication overuse patient by administering botulinum toxin to the patients.

Co-pending application 10/780,180 does not specifically recite that the medication overusers are triptan medication overusers. However, Matthew et al teach that acute medications that are overused include triptans (the Abstract, 2nd column). Thus, Matthew et al teach triptan medication overusers. Matthew et al teach that botulinum toxin was effective in treating patients with medication overuse by reducing the number of chronic migraine and thereby reducing the acute medication use (see the Abstract).

It would be *prima facie* obvious at the time the invention was made to include triptan medications as a part of the genus of medications that can be overused by medication overusers because Matthew et al teach that tripan medications are among the medications overused by patients that experience chromic migraines (see the Abstract). It would be expected barring evidence to the contrary, that botulinum toxin can be used to effectively treat chronic headaches in tripan medication overuse patients.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 6-16, 18-20 and 29 are rejected under 35 U.S.C. 103(a) as unpatentable over Bigal et al *(Cephalagia, 2002, 22, p. 432-438)* in view of *Cephalalgia, An International Journal of Headache*, (Volume 24, Supplement 1, 2004) and further in view of Loder et al *(The Clinical Journal of Pain, 18:S169-S176, 2002)*.

Independent claim 1 is directed to a method of treating an acute pain medication overuse disorder caused by overuse of acute pain medication, the method comprising the step of local administration of between about 1 unit and about 1500 units of a pure botulinum toxin type A or B, wherein the pure botulinum toxin has a molecular weight of about 150 kDa, to a patient with acute pain medication thereby treating the acute pain medication overuse disorder caused by overuse of acute pain medication, wherein the patient takes the medication prior to experiencing pain and experiences pain after the intake of acute pain medication thereby treating the acute pain medication overuse disorder caused by the overuse of acute pain medication.

Dependent claim 29 is drawn to the method of claim 16, wherein the patient experiences a headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months.

Loder et al teach that administration of botulinum toxin decreases that pain and provides relief for patients suffering from chronic daily headaches (see the Abstract and S172-S173).

Loder et al do not specifically teach the claim limitation "wherein the patient experiences a headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months".

Bigal et al teach patients that are medication overusers that suffer from chronic daily headaches (page 434, 1st column, Table 1). Bigal et al teach chronic daily headache (CDH) is a headache lasting more than 4 hours per day and on 15 or more days per month (page 432, 1st column).

Cephalalgia, An International Journal of Headache, Volume 24, Supplement 1, 2004 teach that the most common migraine-like headache occurs on ≥ 15 days per month and occur as a mixture of migraine-like and tension-like headaches (page 94). *Cephalalgia, 2004* teach that these patients overuse migraine drugs and /or analgesics (page 94). *Cephalalgia, 2004* teach that diagnostic criterion is used on ≥ 10 days per month, this translates into 2-3 treatment days a week (page 94).

It would have been prima facie obvious at the time the invention was made to modify the method of treating chronic daily headaches as taught by Loder et al to include patients that have chronic daily headache and are medication overusers

because *Cephalalgia, 2004* teach that medication overuse patients are patients that use migraine or analgesics on ≥ 10 days per month, this translates into 2-3 treatment days a week and Loder et al teach that administration of botulinum toxin decreases that pain and provides relief for patients suffering from chronic daily headaches. It would be expected, absent evidence to the contrary that botulinum toxin would be effective in treating patients with chronic daily headaches (patients that have a headache for at least 4 hours per day) including patients that suffer from medication overuse.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar element according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art that patients that suffer from medication overuse have chronic daily headaches and chronic daily headache patients are patients that have a headache for at least four hours per day for ≥15 days/per month. See Bigal et al. It well known in the art that medication overuse patients are patients that have the diagnostic criterion of headaches on ≥ 10 days per month which translates into 2-3 treatment days a week. See of *Cephalalgia, An International Journal of Headache*, (Volume 24, Supplement 1, 2004). It is also well known in the art to treat patients which suffer from chronic daily headaches with botulinum toxin. See Loder et al.

Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results. The combination of prior art references as combined provided a *prima facie* case of obviousness absent convincing evidence to the contrary.

Status of Claims

5. No claims allowed.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VANESSA L FORD/
Primary Examiner, Art Unit 1645
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